

**Materials Management Process Improvement**  
*A Case Study*  
**INTERPHEX**  
**April 2010**

**TRANSFORMING LIFE SCIENCES**

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 Lonza Biologics, Hopkinton, MA

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**Topics for Today**

- Case Background & Situation
- Project Objectives & Scope
- Approach & Timing
- Deliverables & Results
- Current Status
- Lessons Learned
- Q&A

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### Case Background & Situation

*Lonza is a global leader in providing development and manufacturing services for the pharmaceutical and biotechnology industries...*

- Hopkinton, MA is a microbial biopharmaceuticals site
  - Fast growing and wrestling with how to scale many business processes – many operating processes designed for a business with much lower volumes
  - Recognized that in order to scale activities effectively, business processes that were adequate in the past must be redesigned.
  - Leadership wanted to increase the use of operational excellence tools and lean behaviors to address important business issues
- Materials management initially chosen initial improvement
  - Key “front-end” process that drives downstream performance

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### Case Background & Situation

*Lonza Hopkinton had experienced a number of operating issues that were directly traceable to a lack of robustness in materials management...*

- Out of stock conditions caused by
  - Inaccurate inventory counts in the MRP system
  - Inability to move materials through the receipt and testing processes in a rapid fashion
  - Utilizing materials intended for other customers/campaigns for current work (and not backfilling)

*At the time, the site was capacity constrained, although major construction was underway to alleviate this situation*

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### Case Background & Situation

*As a result of these operating issues, Lonza was experiencing...*

- Difficulty in planning and scheduling suites and resources
- Delays in customer campaigns
  - For the campaign currently in manufacture
  - For other campaigns queued up for manufacture utilizing the same facilities and equipment
- Negative cost impacts

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**Project Objectives & Scope**

*The Materials Management Process improvement initiative was chartered beginning with clear objectives and scope...*

**Objectives:**

- Develop a common understanding of the "As Is" Materials Management process
- Identify and prioritize process improvements
- Develop 60-day action proposals to implement high priority improvements
- Implement initial wave of 60-day action proposals

**Scope:**

*Materials*

- All direct materials (become part of the finished drug product)

*Processes*

- All materials management processes beginning with Bill of Materials development and ending with material disposition
- Includes all sub-processes involved in material receipt, quality control, storage, distribution to manufacturing, and disposition

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## Approach & Timing 3-Day Innovation Workshop

*First, we chartered a cross-functional team to conduct a 3-day innovation workshop to include elements of education and process analysis, ending with development of 60 day action proposals...*

Task	Outcome/Deliverable
<b>Design and Conduct Multi-Day Innovation Workshop -</b> <ul style="list-style-type: none"> <li>Development of "As Is" process maps</li> <li>Identification of process strengths and weaknesses</li> <li>Development of criteria for prioritization</li> <li>Development of prioritized list of opportunities</li> <li>Identification of teams and approaches to address high priority weaknesses</li> <li>Brief executive team on workshop process, outcomes, and next steps</li> </ul>	<ul style="list-style-type: none"> <li>Informed executive team regarding workshop process, outcomes, and next steps</li> <li>Set of metrics for managing and measuring the process</li> <li>Vision statements for future state</li> <li>"Idea bank" of sorted and prioritized ideas</li> <li>Materials Management process maps</li> <li>"As Is" process performance assessment</li> <li>Set of action proposals for 60 day implementation sprints</li> </ul>

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## Approach & Timing 3-Day Innovation Workshop

*Lean & six sigma tools were utilized within the DMAIC structure to understand the current state and innovate the future state...*

<b>D</b> Defects in the Process	➤ Brainstorm all of our frustrations out onto one page
<b>A</b> As-Is Process Map	➤ Define & document as-is process so we're all is on same page, talking about the same process
<b>M</b> As-Is Performance	➤ Identify metrics and estimate current performance
<b>I</b> Ideal Performance	➤ What would the process look like if all of our metrics were perfect?
List of Stakeholders	➤ Who are our customers, "doer"s, suppliers & shareholders?
<b>A</b> Stakeholder Requirements	➤ How can we <i>delight</i> our stakeholders?
Vision for Change	➤ What constraints are keeping us from delighting our stakeholders?
Lean Innovation	➤ How can we apply existing Lean tools to our process innovation?
<b>I</b> Converge on top ideas	➤ Funnel the long list of great ideas into top 3-5 actionable ideas
<b>C</b> Action proposals	➤ Develop well-thought out, high-level, team action proposals

*Supporting this structure were strong sponsor support, a clear charter, expert knowledge, focused brainstorming, team consensus-building, animated discussion and educational exercises.*

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## Approach & Timing 3-Day Innovation Workshop

*The 3 days were rigorously structured to bring the team to well-defined action plans for "Materials Management" improvements...*

DAY ONE	DAY TWO	DAY THREE
Continental Breakfast	Continental Breakfast	Continental Breakfast
Workshop Introduction <ul style="list-style-type: none"> <li>Workshop logistics</li> <li>Charter, roles &amp; expectations</li> </ul>	<b>MEASURE</b> <ul style="list-style-type: none"> <li>Assess process performance &amp; conduct value analysis</li> </ul>	<b>INNOVATE</b> <ul style="list-style-type: none"> <li>Develop a new process vision</li> </ul>
Innovation Basics <ul style="list-style-type: none"> <li>Innovation concepts &amp; challenges</li> </ul>	Lunch	<ul style="list-style-type: none"> <li>Identify &amp; Prioritize – top ideas</li> </ul>
Lunch	<b>ANALYZE</b> <ul style="list-style-type: none"> <li>Identify process requirements &amp; dig into root causes of problems</li> </ul>	Lunch
<b>DEFINE</b> <ul style="list-style-type: none"> <li>Define &amp; map the process mission, activities, and performance system</li> </ul>		<b>CONTROL</b> <ul style="list-style-type: none"> <li>Formulate action proposals &amp; next steps</li> <li>Workshop Summary</li> </ul>

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## Approach & Timing 3-Day Innovation Workshop

*To ensure an efficient and effective workshop experience, a few tasks were completed prior to the actual workshop...*

- Identify team Champion and Steering Committee
- Identify & engage team members
- Formal chartering including finalizing scope and objectives
- Customize workshop templates/materials
- Collecting appropriate data and baseline information

**Workshop Preparation**

- D Team
- Finalize Charter
- Customize Materials
- Baselining

◆ Innovation Workshop

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## Approach & Timing 60 Day Sprints

*The innovation workshop was followed immediately by a 60 day Sprint, structured to ensure that the improvements identified in the workshop were actually made and benefits were realized...*

What was required?	How did the 60 Day Sprint accomplish it?
Maintain momentum	<ul style="list-style-type: none"> <li>• Ensured formal team structures, participation, meeting frequency, and roles</li> <li>• Continued to provide team tools and direct coordination support for this phase</li> </ul>
Remove obstacles	<ul style="list-style-type: none"> <li>• Active and coordinated team involvement</li> <li>• Direct lines of communication with Steering Committee</li> </ul>
Keep people and the organization engaged	<ul style="list-style-type: none"> <li>• Scheduled and structured team meetings and activities</li> <li>• Structured interactions with Steering Committee and key Stakeholders</li> <li>• Continued communications across the organization on activities, progress, and results</li> </ul>

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## Approach & Timing 60 Day Sprints

*The action teams and consulting coaches worked together on a weekly cycle to ensure progress and momentum*

- Weekly Team Meeting
- Teams & Individuals Execute Tasks
- Sub-Team Work Sessions (as needed)

Week 1 | Week 2

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## Approach & Timing 60 Day Sprints

*At the beginning of the Sprint a map of topics and activities for the weekly team meetings was developed to help drive progress...*

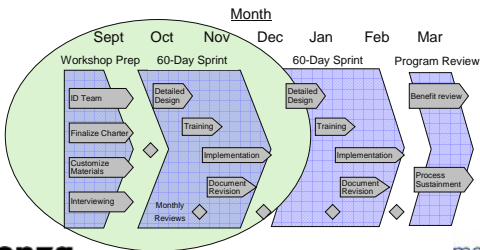
	Date	Review	Education	Working Session	Tasks Assigned
Week 1	10/17 & 21	Steering Committee Report-Out & Guidance	How We'll Work Together	Work plan	Execution
Week 2	10/28	Progress to Plan	Stakeholder Role Decision Process	Communications Plan Introduction to Stakeholders	
Week 3	11/4	Progress to Plan SC Mtg Feedback	30-Day Progress Check Template Education on Specific Tools		
Week 4	11/11	Progress to Plan Review 30-Day Report			Champions to Complete 30-Day Reports
Week 5	11/18	Debrief from 30-Day Check-in Progress to Plan	Proposal Structure & Template		Schedule Stakeholder Endorsement Mtgs
Week 6	12/2	Progress to Plan	Implementation & Control Planning		Complete Proposals
Week 7	12/9	Progress to Plan Stakeholder Endorsement Mtgs			
Week 8	12/16	Progress to Plan Stakeholder Endorsement Mtgs	Post-Breakthrough Planning		Complete Final Report

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## Approach & Timing

*The flow and timeline for the Workshop and Initial 60 Day Sprint looked as follows, followed by regular benefits reviews to ensure follow up and sustainment...*



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## Materials Matters (M&M) Team Charter


*The team set out to improve the end-to-end GMP Materials Management process in order to...*

- Develop a common understanding of the "As Is" Materials Management process
- Decrease cycle time and reduce wasted effort in the process
- Create and implement metrics to sustain process improvements
- Provide a successful improvement effort to serve as the model for future cross-functional improvement efforts



*The deliverables from this workshop were...*

- Set of improvement ideas to move forward into implementation
- Action plans, teams, and champions to drive the implementation efforts for the next 60 days
- "Bank" of additional high potential improvement opportunities for future implementation

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## Materials Matters (M&M) Team Charter

*In order to guide its work, the team also identified the purpose of the Materials Management process and process boundaries...*

**PURPOSE** To provide compliant GMP raw materials in the right quantities to meet established schedules in Manufacturing

**START POINT** Stable Bill of Materials available for Production

**END POINT** Material Issue to manufacturing and the decrementing of inventory from SAP

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## Materials Matters (M&M) Workshop Activities and Outcomes

*During the 3 days, the team went from a standing start to defining innovative improvements...*

- Defined and mapped the inputs, outputs, suppliers, customers, activities, and roles within the Materials Management process
- Conducted "value-added" vs. "hidden factory waste" analysis of process activities and discovered dramatic improvement opportunities if the "hidden factory" could be eliminated
- Assessed process performance for cycle time and labor
- Identified process stakeholders and their requirements
- Used the "5-Why's" technique to dig into root causes of barriers to improved performance
- Developed a vision for an improved Materials Management process
- Applied Lean Innovation techniques to design the improved process
- Sorted and prioritized the best ideas to identify opportunities to move forward
- Developed a set of action proposals that show potential for big gains within 60 days

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## Materials Matters (M&M) Workshop Activities and Outcomes

*Each action proposal was developed utilizing a common template.  
For example...*

**PROPOSAL:**

The problem...  
The rationale for RM sampling plans in many cases is based on historical events, which may be outdated, resulting in excessive sampling and inspection effort and cycle time.

Our proposed solution...  
This proposal is to rationalize and reduce sampling plans for RM, where possible, based on assessment of risk and understanding of compliance requirements.

**EXPECTED BENEFITS:**  
Significant benefits are expected from this proposal:

- Reduced sampling, inspection & testing effort and cost
- Fewer testing errors
- Better able to measure non-conformances
- Reduced RM disposition and hold times

**INNOVATION IDEAS:**

This proposal includes several new ideas:

- Review Lonza, client and regulatory sampling requirements to understand true sampling requirements vs Lonza practice
- Apply statistical techniques to justify reducing sampling frequency and volume, where appropriate
- Evaluate potential supplier sampling testing program
- Implement direct dock-to-stock process, as appropriate, for certain low-risk materials

**POTENTIAL RISKS:**

There may also be some risks which the team will need to address:

- Need to justify change to regulatory agencies
- May result in missing some non-conformances
- Potential for misalignment with global Lonza standards

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## Materials Matters (M&M) Workshop Activities and Outcomes

*Action Proposal continued...*

**ACTION TEAM:**

This is the team that will take this proposal forward:

- Kathy Burri (Team champion)
- Denise Knight
- Jen Johnston
- Jason Martin

**KEY STAKEHOLDERS:**

Involvement of the right people will be essential for success:

- Kathy Burri (OA)
- Jason Martin (QC)
- Kelly O'Hare
- Hemant Kumar

**60-DAY ACTION PLAN:**

The team is ready to move forward on this proposal immediately:

Preliminary Action Item

Obtain stakeholder and steering committee endorsement

Review Lonza, client and regulatory sampling requirements

Evaluate categories of RMS

Design sampling plans for different categories of RMS

Evaluate potential supplier sampling testing program

30-day management review

Create/revise, implement and train on relevant SOPs

Develop Control Plan to sustain improvements

60-day report-out

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## Deliverables and Results

### Rationalize and Reduce Sampling Plans

The sampling plan framework was supported by a set of clear definitions and examples of materials in each category...

Raw Material: API Starting Material/Excipient	Active material, intermediate or API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API Starting Material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house. API Starting Materials are normally of defined chemical properties and structure, although not generally part of the API structural fragment. Lonza LSP includes excipients in this category when they are critical attributes in the final formulation of the bulk drug substance.		
Raw Material: Chemical	Active material which is not an excipient, API or start of the manufacturing process of an API.	Material Category	Material Examples
Consumable: Traceable	A subset of consumables which are likely to have a lot and thus require additional control to govern API quality and which have to be manufactured in batches recorded in a batch record for enhanced lot traceability.	Raw Materials: API Starting Materials and Excipients	All bulk formulation materials, example Sodium Chloride, Polysorbate 80/20.
Consumable: Process Aid	A subset of consumables that are not in direct contact as an aid in the manufacture of an intermediate or a formulation participate in a chemical or biological activated carbon, facility cleaning or distilling etc.	Raw Materials: Chemicals	Media, Buffers, Amino Acids, Trace Elements, Vitamins, Antioxidants, Solvents, Acids/Bases, Process Gases (bulk or cylinders), COP solutions, animal derived materials.
		Consumables: Traceables	Primary & Secondary Packaging Materials, Water Reduction Filters, UF/Crossflow/Pool Filtration Filters, Sterilizing Filters, Process Filters, Bags used for process solutions (other than waste), Spent Filters, Bulk Fill Container, Closures, Carboys, Nitrogen Containers, Bioprocess Containers/Overbags, Traceable Sp. Product Contact Tubing, Flex Containers, Containers, Flex Pipes
		Consumables: ProcessAids	Sampling Bags/Equipment, Pipettes / Pipette Tips, Cleaning Supplies, Site Purches, Sampling or Dispensing Devices, Facility Cleaning or Disinfection Chemicals, Vent Filters, Filter Integrity Test Kits, Wipes, Non-Product Contact Tubing, Brushes

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## Deliverables and Results

### Rationalize and Reduce Sampling Plans

At the end of the initial 60-Day Sprint the action team had identified and confirmed the following improvement opportunities and was on track to achieving them...

Metric	Baseline	Projected	Improvement
Sample Reduction	3901 samples	2108 samples	46%
Cycle Time (part number X)	3 days	0 days	100%
Cycle Time (part number Y)	4 days	3 days	25%

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## Deliverables and Results

### Rationalize and Reduce Sampling Plans

In addition to cycle time reduction, improvement in these metrics areas directly translates to real dollar benefits...

Improvements to the program when compared to a baseline period of 10/2007 – 10/2008:

- Removed redundant QC inspection for Traceables (14 part number), resulting in reduction of 378 person-hours
- Overall 46% reduction in samples

This accounts for about 1000 person-hours that can be redeployed to other value-adding activity

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## Deliverables and Results

### Rationalize and Reduce Sampling Plans

*A number of activities remained to be completed after the initial 60-Day Sprint to ensure full realization of benefits and move the project to the next phase...*

Activity	Rationale for Addressing	Next Steps
Complete RMS revisions for remainder of raw materials purchased in the last year	To complete implementation and gain full realization of cost benefit	Maintain team to complete RMS revisions
Identify effective RMSs that have not been ordered in the last year or more and make them inactive	Remove added maintenance of unused or infrequently used vendors/raw materials from the system to minimize impact to supplier qualification program	Utilize data gathered from this effort as a starting point. Harmonize with data gathered from Supplier Qualification Program review
Examine materials identified as excipients	Some materials identified as excipients are used for purposes other than final formulation buffer	Provide information to supply chain and manufacturing to make the appropriate assessments and implement cost reduction strategy

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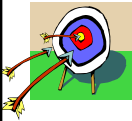
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## Deliverables and Results

### Better Utilize SAP within the MM Process



**PROPOSAL:**  
**The problem...**  
 RMs are not always decremented in SAP at time of use and quality groups have limited access to RM information in SAP. This causes inaccurate inventories, redundant paperwork & databases, miscommunication and rework.

**The proposed solution...**  
 This proposal is to enable on-time SAP RM transactions and provide QA and QC access to existing SAP capabilities.

**EXPECTED BENEFITS:**  
**Significant benefits are expected from this proposal:**

- Up-to-date and accurate inventory
- Fewer material shortages, expedites and manufacturing delays.
- Improved cross-functional communication
- Elimination of redundant data and transactions

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## Deliverables and Results

### Better Utilize SAP within the MM Process

*The action team had numerous key accomplishments during the 60-Day Sprint...*

**First 30 Days**

- Developed required materials for SAP training.
- Set up a training facility and began implementation of a training program for new users to help bolster the ranks of trained people.
- Conducted a baseline physical inventory for all suites to ensure SAP inventories were correct.

**Last 30 Days**

- Trained 9 new SAP users (bringing the total number of users to 18)
- Developed key metrics
- Facilitated four stakeholder meetings and obtained stakeholder commitments to improved frequency and rigor of SAP use by Manufacturing.

**A key result was accurate SAP data and increased confidence and trust in the reliability of that data**

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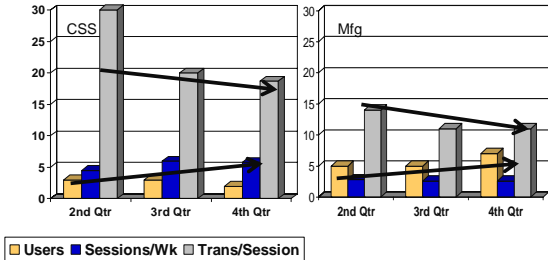
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**Deliverables and Results**  
Better Utilize SAP within the MM Process

*A look at baseline data from 2008 indicates the opportunity to reduce transactions per SAP session while raising the number of sessions per week...*



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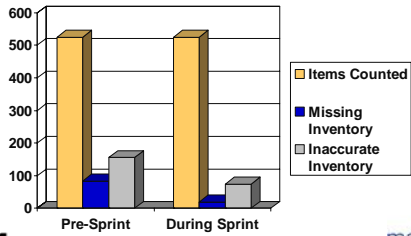
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**Deliverables and Results**  
Better Utilize SAP within the MM Process

*Improved SAP training and usage led to early-on improvement in resolution and reduction regarding inventory errors...*



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**Deliverables and Results**  
Better Utilize SAP within the MM Process

*Benefit was recognized from not requiring physical verification of materials due to improved confidence in accuracy of SAP inventory*

- Estimated days/week spent verifying and resolving material issues
  - Manufacturing - 1.5 days/week
  - Material Control - 1.0 day/week
  - Purchasing - 1.5 days/week
- Initially, we estimated this 4 days/week would reduce to 3 days/week

*This equates to about a \$50,000 annualized opportunity for labor redeployment*

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## Deliverables and Results

### Better Utilize SAP within the MM Process

*Additionally, there were adverse events that were avoided due to this action team's work, for example...*

Potential Loss of nearly \$20,000 in Bioprocessing Bags -

- Situation
  - During inventory it was discovered these bags were missing from Mfg.
  - Site was unaware of where the bags were or how to disposition them
- Resolution
  - During SAP training, the user of these bags recognized the issue and acknowledged improper (Non-SAP) transactions
  - As a result,
    - Site was able to appropriately charge the customer for the material
    - Site did not absorb any scrap

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## Deliverables and Results

### Better Utilize SAP within the MM Process

*Since monitoring the ongoing sustainment of initial behavior changes was key to this action team's work, a process control plan was put in place...*

Process Performance Checkpoint	Control Limit/Target Performance	Data Collection Tool	Champion	Frequency of Check
Number of sessions per week	Continued increase in the number of sessions	Data collection in graphical form	Alex	Monthly through first quarter 2009
Number of transactions per session	Continued decrease in number of transactions per session	Data collection in graphical form	Alex	Monthly through first quarter 2009
Number of Users	Continued increase in number of users	Data collection in graphical form	Alex	Monthly through first quarter 2009
Inventory Accuracy	Continued reduction in inventory errors	Data collection in graphical form	Larry	Monthly through first quarter 2009

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## Lessons Learned

- Active involvement of site leadership is critical to implementing and sustaining change.
  - Leadership involvement demonstrates the importance of the initiative.
  - Site leadership involvement reinforces the "lead by example" element of change which is a common theme in many town hall meetings.
- Proper resources must be made available
  - Time availability to participate is critical.
  - Change cannot be a side-effort; it requires resources with large amounts of time and energy to dedicate.
- During the process of innovation, all avenues/possibilities must be open to consideration.
  - By having all possibilities available, all options were explored and suggestions weren't bound by limitations.
  - This helps ensure significant change occurs, not just small, incremental change.

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## Maxiom Group Overview

- Maxiom Group is a business and information technology consulting firm exclusively serving the life sciences industry
- Our clients include *emerging, established, and mature* Biotechnology, Pharmaceutical, Diagnostic and Medical Device companies
- Maxiom Group helps life science companies transform their strategies, business processes, and business systems to achieve excellence at each stage of their life cycle
  - From drug discovery to clinical development
  - From clinical development to commercial launch
  - From commercial launch to market leadership
- Clients rely on our *Focus, Insight and Approach* to guide them in transforming their business and in addressing their ongoing business challenges

Proprietary and Confidential 45

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